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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS-2008-0085]

RIN 0579-AD17

Importation of Ovine Meat From Uruguay

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) ovine meat from Uruguay. A risk assessment that we have prepared indicates that fresh (chilled or frozen) ovine meat can safely be imported from Uruguay under these conditions. This action will allow the importation of fresh ovine meat from Uruguay into the United States while continuing to protect the United States against the introduction of foot-and-mouth disease.

EFFECTIVE DATE: [Insert date 15 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Silvia Kreindel, Senior Staff Veterinarian, Regionalization Evaluation Services Staff, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 851-3313.

## SUPPLEMENTARY INFORMATION:

### Background

Under the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 et seq.), the Secretary of Agriculture may prohibit or restrict the importation of any animal or article if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.

Pursuant to this Act, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases not currently present or prevalent in this country. The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of specified animals and animal products to prevent the introduction into the United States of various animal diseases, including rinderpest and foot-and-mouth disease (FMD). These are dangerous and destructive communicable diseases of ruminants and swine.

Section 94.1 of the regulations contains criteria for APHIS recognition of foreign regions as free of rinderpest and FMD. Section 94.11 restricts the importation of ruminants and swine and their meat and certain other products from regions that are declared free of rinderpest and FMD but that nonetheless present a disease risk because of the regions' proximity to or trading relationships with regions affected with rinderpest or FMD. Regions APHIS has declared free of FMD and/or rinderpest, and regions declared free of FMD and rinderpest that are subject to the restrictions in § 94.11, are listed on the APHIS Web site at [http://www.aphis.usda.gov/import\\_export/animals/animal\\_disease\\_status.shtml](http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml).

Because vaccination for FMD may not provide complete protection to livestock, and because it can be difficult to quickly detect FMD in animals vaccinated for FMD, APHIS does not recognize regions that vaccinate animals for FMD as free of the disease. Uruguay vaccinates cattle for FMD. Therefore, although Uruguay has not had a case of FMD since 2001, APHIS does not recognize Uruguay as a region free of FMD. Based on a final rule effective and published in the Federal Register on May 29, 2003 (68 FR 31940-31949, Docket No. 02-109-3), however, APHIS allows the importation of fresh (chilled or frozen) beef from Uruguay under certain conditions that mitigate the FMD risks associated with this product. The conditions are set out in § 94.22 of the regulations.

In a proposed rule<sup>1</sup> published in the Federal Register on February 24, 2011 (76 FR 10266-10269, Docket No. APHIS-2008-0085), we proposed to also allow the importation of fresh ovine (sheep) meat from Uruguay under conditions identical to those currently required for the importation of fresh beef, except for one change noted below. The proposed conditions were as follows:

- The meat is from animals that have been born, raised, and slaughtered in Uruguay.
- If FMD is detected anywhere in Uruguay, the export of beef and ovine meat from all of Uruguay to the United States is prohibited until at least 12 months have elapsed since the depopulation, cleaning, and disinfection of the last infected premises. [The current requirement for fresh beef is that FMD has not been diagnosed in Uruguay within the previous 12 months.]

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<sup>1</sup> To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0085>.

- The meat came from animals that originated from premises where FMD has not been present during the lifetime of any animals slaughtered for the export of meat to the United States.
- The meat came from animals that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.
- The meat came from animals that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.
- The meat consists only of parts of the animal's carcass that are, by standard practice, placed in a chiller for maturation after slaughter. No part of the animal's heads, feet, hooves, or internal organs may be exported (and for bovines, the hump is also excluded).
- All bone and visually identifiable blood clots and lymphoid tissue have been removed from the meat.
- The meat has not been in contact with meat from regions other than those APHIS recognizes as free of FMD.
- The meat came from carcasses that were allowed to mature at 40 to 50 °F (4 to 10 °C) for a minimum of 36 hours after slaughter and that reached a pH of 5.8 or less in the loin muscle at the end of the maturation period. Measurements for pH must be taken at the middle of both longissimus dorsi muscles. Any carcass in which the pH does not reach 5.8 or less may be allowed to mature an additional 24 hours and be retested, and, if the carcass still has not reached a pH of 5.8 or less after 60 hours, the meat from the carcass may not be exported to the United States.

- An authorized veterinary official of the Government of Uruguay certifies on the foreign meat inspection certificate that the above conditions have been met.
- The establishment in which the animals are slaughtered allows periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative.

We solicited comments concerning the proposed rule for 60 days ending April 25, 2011. We received 10 comments by that date. They were from organizations representing Uruguayan meat packers, meat exporters, and sheep producers; Uruguay's Ministry of Livestock, Agriculture, and Fisheries (MGAP); organizations representing meat importers within the United States and the U.S. sheep industry; and several private citizens.

Four of the commenters supported the rule as written. Two commenters objected to the proposal. The remaining commenters favored the importation of fresh (chilled or frozen) ovine meat from Uruguay but requested clarifications or modifications to the rule or its supporting documents. The issues raised by commenters are discussed below, by topic.

#### The Risk Assessment

One commenter requested that we reexamine our risk assessment that we prepared regarding the importation of fresh (chilled or frozen) ovine meat from Uruguay. The same commenter and one other requested that we conduct an additional site visit. They expressed concern that changes may have occurred in Uruguay's risk factors for FMD and in Uruguay's ability to prevent and mitigate FMD risk since we completed the risk assessment. Neither commenter mentioned any specific changes that should be investigated. One commenter also urged APHIS to specify a schedule requiring follow-up and ongoing reporting from Uruguay on FMD risk and the implementation of risk mitigation measures.

We have reevaluated the information in the assessment and have determined that it still provides an appropriate basis for our conclusion that the FMD risk from importing fresh (chilled or frozen) maturated and deboned ovine meat from Uruguay is low and that such meat may be safely imported into the United States. Based on our review of the assessment, we do not think an additional site visit is warranted prior to finalizing the proposed rule.

Regarding the need for ongoing reporting from Uruguay, as part of the implementation of this final rule, we will require MGAP to submit an operational workplan, subject to APHIS' approval, that details activities that MGAP will carry out to meet the requirements of the regulations. Additionally, paragraph (k) of § 94.22 requires the establishment in Uruguay in which the bovines and sheep are slaughtered to allow an APHIS representative to make periodic on-site evaluations and subsequent inspections of its facilities, records, and operations. MGAP's operational workplan will have to specifically authorize the on-site evaluations and inspections of facilities, records, and operations. APHIS regulations in 9 CFR part 92 also address the potential need for APHIS to obtain additional information from a region after APHIS has granted the region animal health status. In particular, under § 92.2(g), a region may be required to submit additional information pertaining to animal health status or allow APHIS to conduct additional information collection activities in order for that region to maintain its animal health status. We believe these provisions, collectively, will enable APHIS to satisfactorily monitor the fresh meat import program.

#### Prohibitions on the Importation of Meat Following an FMD Outbreak

One commenter stated that the proposed prohibition on the export of fresh beef or ovine meat to the United States until 12 months after depopulation, cleaning, and disinfection of the last premises involved in an FMD outbreak does not merely clarify existing policy, as APHIS

stated in its proposed rule. Rather, since the current requirement for fresh beef from Uruguay is 12 months following the last diagnosis of FMD, the proposed change would impose new, more stringent requirements for the importation of beef from Uruguay. The commenter also stated that, to be consistent with standards of the World Organization for Animal Health (OIE) and the principle of regionalization, the prohibition on exports should be limited to 6 months and apply only to exports from restricted zones for FMD that would be established by MGAP in response to a limited outbreak in Uruguay, rather than to exports from anywhere in the country.

FMD is a significant disease of livestock, and its introduction into the United States could have a lasting deleterious effect on the U.S. agricultural economy. In regions that vaccinate animals for FMD, it can be difficult to detect the disease, and APHIS believes that sufficient time must pass to ensure that ruminant products exported from the region will not be a vector of the FMD virus. Depopulation, cleaning, and disinfection of infected premises are standard practices in stamping out FMD. After considering this comment, though, we have decided that there is no need to build this language into the rule. If a country experiences an outbreak of FMD and there is no diagnosis of the disease in a 12-month period following the last case, APHIS considers this to be sufficient reason to conclude that the disease did not spread. Therefore, we will leave the provision as it is currently worded in the provisions for fresh beef: Foot-and-mouth disease has not been diagnosed in Uruguay within the previous 12 months.

Consistent with the OIE principle of regionalization, APHIS regulations in 9 CFR part 92 explain how a country may request APHIS recognition of regions within its borders. In requesting to export fresh (chilled or frozen) ovine meat to the United States, Uruguay did not ask APHIS to recognize restricted zones as regions in the event of an FMD outbreak, or provide

sufficient information for us to evaluate the risk of disease spread from such zones in order to allow for regionalization at that level.

#### The Maturation Process

One commenter questioned the need for a minimum 36-hour maturation period. Noting that the key indicator for ensuring deactivation of the FMD virus is a pH of 6.0 or lower, the commenter stated that if a pH of 5.8 is reached within 24 hours, then the virus will be deactivated and there is no need for an additional holding period. The commenter stated that the 36-hour holding period creates logistical problems for the packinghouses, which must hold carcasses in chillers, and is inconsistent with the requirements of other countries that apply a pH requirement of either 5.8 or 6.0, with a required holding period of 24 hours, for the export of Uruguayan meat to their markets. The commenter urged to require a minimum holding period of 24 hours.

We agree with the commenter that the acidification necessary to inactivate the FMD virus can be achieved within 24 hours and are modifying § 94.22(i) in this final rule accordingly. Twenty-four hours will be the minimum time required for maturation. If the required pH is not achieved during 24 hours, the meat may continue to mature for up to an additional 24 hours (48 hours total). Any meat that has not achieved the required pH level in that amount of time may not be exported to the United States.

We have also determined that a pH lower than 6.0 in the longissimus dorsi, in conjunction with other conditions included in this final rule, is a good indicator of FMD virus inactivation. Our review of the literature revealed that acidification at that level is sufficient to inactivate FMD virus in muscle tissue of viremic cattle. Furthermore, over 30 years of epidemiological data show that there is no evidence that importation of fresh beef that reached a pH of less than 6.0 under conditions that are already incorporated into the regulations and that



are analogous to those contained in this final rule (e.g., antemortem and postmortem inspection, lymph node removal, deboning, and maturation) have been associated with outbreaks of FMD. Therefore, in § 94.22(i) of this final rule, the meat will be required to reach a pH of less than 6.0, rather than 5.8 or less, as we had originally proposed.

#### Removal of Bones

One commenter stated that there is no basis for limiting approval for export of ovine meat to boneless products because there has been no evidence of FMD in sheep in Uruguay since the country requested access for fresh beef exports in 2003.

We proposed to require that all bone, as well as visually identifiable blood clots and lymphoid tissue, be removed from fresh ovine meat prior to export to the United States from Uruguay. The same requirement has been in place for fresh beef exported from Uruguay.

As we noted in both our risk assessment and in the proposed rule, although the last case of FMD in Uruguay was in 2001, FMD is endemic in areas of South America surrounding Uruguay, and there is, accordingly, a risk that FMD will be reintroduced into the country. Uruguay vaccinates cattle for FMD in recognition of that risk. Each of the conditions we proposed, including this one, addresses a critical point in the pre-export process, from selection of an animal for slaughter to carcass processing and maturation, where FMD risk can be mitigated. The conditions were selected based on known modes of transmission and physical characteristics of the FMD virus. Maturation of the meat addresses the risk, however small, of FMD virus being present in the animal at slaughter. The removal of bones and visually identifiable blood clots and lymphoid tissue is necessary because any FMD virus these parts might potentially harbor may not be inactivated by the maturation process.

### Certification by Veterinary Officials in Uruguay

One commenter expressed concern about our proposed requirement that an authorized veterinary official of the Government of Uruguay certify that all conditions for the importation of beef and ovine meat have been met. The commenter stated that veterinary officials could be bribed or otherwise induced to falsely certify meat as meeting the conditions for importation, which could pose a risk of introducing FMD into the United States.

As explained in response to another comment, APHIS will be monitoring the fresh meat export program. If we determine that inspection certificates are being deliberately falsified, we may take measures pursuant to our authority under the AHPA to ensure that beef or ovine meat from Uruguay does not present a risk of introducing FMD into the United States. Such measures may include prohibiting the importation of fresh beef and ovine meat from Uruguay.

### Labeling of Ovine Meat

One commenter asked whether ovine meat imported as proposed would be labeled and marketed in the United States as “fresh.” The commenter stated that, because the product would have been chilled or frozen, it would not meet the average U.S. consumer’s definition of “fresh” and should not be marketed as such. The commenter also asked whether ovine meat imported from Uruguay into the United States would be subject to country-of-origin labeling.

As used in the regulations, the term “fresh” simply means that the meat is imported without having been cooked or cured as otherwise required of beef or ovine meat from regions not recognized as free of FMD. APHIS does not regulate the marketing of meat in the United States. Regarding country-of-origin labeling, the Country of Origin Labeling (COOL) law requires retailers to notify their customers of the country of origin for all commodities covered under this law. Muscle cuts of beef and lamb, as well as ground beef and ground lamb, are

covered. The COOL law is enforced by USDA's Agricultural Marketing Service and Food Safety and Inspection Service. The COOL law is not related to animal health, but rather, is a consumer information program, and thus has no bearing on this rulemaking.

#### Goat Meat

One commenter expressed concern that inspectors may not know the difference between a goat kid carcass and a lamb kid carcass.

Establishments in Uruguay that prepare ovine meat for export slaughter the sheep. Live sheep are easily distinguishable from live goats. It is unlikely that a facility would slaughter a goat and present its meat as ovine meat. As discussed previously, APHIS will be monitoring the fresh meat export program, including through on-site evaluations and inspections of facilities, records, and operations.

#### Chronic Wasting Disease

One commenter objected to the lack of inspection for chronic wasting disease.

Chronic wasting disease (CWD) is a transmissible spongiform encephalopathy of cervids (members of Cervidae, the deer family). Species known to be susceptible to CWD via natural routes of transmission include Rocky Mountain elk, mule deer, white-tailed deer, black-tailed deer, and moose. There is no evidence that CWD is transmissible under natural conditions to any other ruminant species, including cattle and sheep, and, therefore, no need for any CWD-related safeguards.

#### Miscellaneous

We have made minor editorial changes to the regulatory text in § 94.22 for clarity. These include replacing “and” with “or” in the following phrases: “beef and ovine meat,” “bovines and

sheep,” and “bovine parts and ovine parts,” and changing “infected premises” to “affected premises.”

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

#### Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the Federal Register.

This rule will allow the importation of fresh ovine meat from Uruguay into the United States under conditions that will continue to protect the United States against the introduction of FMD.

We have determined that approximately 2 weeks are needed to ensure that APHIS and Department of Homeland Security, Bureau of Customs and Border Protection, personnel at ports of entry receive official notice of this change in the regulations. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective 15 days after publication in the Federal Register.

#### Executive Order 12866 and the Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

This rule will allow the importation of fresh (chilled or frozen) lamb and mutton from Uruguay under certain conditions. U.S. entities potentially affected by the rule would be sheep farmers and establishments primarily engaged in processing meat and meat products from purchased meat, most of which are small entities under Small Business Administration standards.

U.S. production of lamb and mutton averaged 79,561 metric tons (MT) over the 5 years, 2006-2010. Over this same period, imports averaged almost 75,100 MT (equivalent to about 94 percent of U.S. production). Uruguay expects its annual lamb and mutton exports to the United States not to exceed 2,000 MT. This quantity is equivalent to less than 3 percent of U.S. lamb and mutton imports and less than 2 percent of U.S. domestic supply of these commodities. A percentage of the imports from Uruguay are likely to displace some of the lamb and mutton imported from existing foreign suppliers, further dampening any possible effects for U.S. businesses.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the

importation of ovine meat from Uruguay under the conditions specified in the rule will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment and finding of no significant impact may be viewed on the Regulations.gov Web site.<sup>2</sup> Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799-7039 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under FOR FURTHER INFORMATION CONTACT.

#### Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579-0372.

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<sup>2</sup> Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0085>. The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

## E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

### List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, NEWCASTLE DISEASE, HIGHLY PATHOGENIC AVIAN INFLUENZA, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. Section 94.1 is amended by revising paragraph (b)(4) and the introductory text of paragraph (d) to read as follows:

§ 94.1 Regions where rinderpest or foot-and-mouth disease exists; importations prohibited.

\* \* \* \* \*

(b) \* \* \*

(4) Except as provided in § 94.22 for fresh (chilled or frozen) beef and ovine meat from Uruguay.

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(d) Except as otherwise provided in this part, fresh (chilled or frozen) meat of ruminants or swine raised and slaughtered in a region free of foot-and-mouth disease and rinderpest, as designated in paragraph (a) of this section, and fresh (chilled or frozen) beef and ovine meat exported from Uruguay in accordance with § 94.22, which during shipment to the United States enters a port or otherwise transits a region where rinderpest or foot-and-mouth disease exists, may be imported provided that all of the following conditions are met:

\* \* \* \* \*

3. Section 94.22 is revised to read as follows:

§ 94.22 Restrictions on importation of beef and ovine meat from Uruguay.

Notwithstanding any other provisions of this part, fresh (chilled or frozen) beef and ovine meat from Uruguay may be exported to the United States under the following conditions:

(a) The meat is beef or ovine meat from animals that have been born, raised, and slaughtered in Uruguay.

(b) Foot-and-mouth disease has not been diagnosed in Uruguay within the previous 12 months.

(c) The meat comes from bovines or sheep that originate from premises where foot-and-mouth disease has not been present during the lifetime of any bovines and sheep slaughtered for the export of beef and ovine meat to the United States.

(d) The meat comes from bovines or sheep that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.



(e) The meat comes from bovines or sheep that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.

(f) The meat consists only of bovine parts or ovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter. The bovine and ovine parts that may not be imported include all parts of the head, feet, hump, hooves, and internal organs.

(g) All bone and visually identifiable blood clots and lymphoid tissue have been removed from the meat.

(h) The meat has not been in contact with meat from regions other than those listed as free of foot-and-mouth disease and rinderpest under § 94.1(a).

(i) The meat comes from carcasses that were allowed to mature at 40 to 50 °F (4 to 10 °C) for a minimum of 24 hours after slaughter and that reached a pH below 6.0 in the loin muscle at the end of the maturation period. Measurements for pH must be taken at the middle of both longissimus dorsi muscles. Any carcass in which the pH does not reach less than 6.0 may be allowed to mature an additional 24 hours and be retested, and, if the carcass still has not reached a pH of less than 6.0 after 48 hours, the meat from the carcass may not be exported to the United States.

(j) An authorized veterinary official of the Government of Uruguay certifies on the foreign meat inspection certificate that the above conditions have been met.

(k) The establishment in which the bovines and sheep are slaughtered allows periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative.

(Approved by the Office of Management and Budget under control number 0579-0372)

Done in Washington, DC, this 7<sup>th</sup> day of November 2013.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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